

REMARKS

Claims 1-3, 5-10, 13-28, and 30-53 are presently pending.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of June 6, 2006 the following actions were taken:

- (1) The Examiner withdrew the objections to the abstract and claims 39 and 48;
- (2) The Examiner withdrew the 35 U.S.C. 112 first paragraph rejection to claims 5-10 and the obviousness-type double patenting rejection to claims 1-13, 17-30, 33-37, 40-46, and 49-51;
- (3) Claims 1-4 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yukiyoishi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");
- (4) Claims 1-4 and 12 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");
- (5) Claims 1-5, 17-19, 27-29, 34-36, 41-45, and 50-53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");
- (6) Claims 1-5, 11, 17, 20-22, 26-29, 34-36, 41-45, and 52-53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");
- (7) Claims 1-4, 17-22, 24-29, 43-45, 50-51 and 53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427");
- (8) Claims 20-23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper");
- (9) Claims 1, 13-17, and 30-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored

by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi");

(10) Claims 34, 37-40, 43 and 46-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of Izumi;

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-5, 11-12, 17-22, 24-29, 34-36, 41-45, and 50-53 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

Composition Claims 1 and 17

The Examiner has rejected claim 1 and 17 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, none of the references set forth a non-GMO metal amino acid chelate composition. This being stated, the Applicant previously amended the composition claims to provide that the amino acid chelates have an amino acid to metal molar ratio from about 2:1 to 3:1, and the chelates are fully coordinated. The Examiner has maintained all of the 102 rejections from the prior office action, even though at least Lumb and Nakamoto do not meet this additional requirement.

Specifically, the Lumb and Nakamoto references clearly identify waters of hydration in their reaction schemes as opposed to a fully coordinated chelate. See Lumb, page 4532, and Nakamoto, page 693. Furthermore, there is considerable doubt that either of these references formed chelates at all. Actual experimental conditions that are used to make these “chelates” are sparse at best. Nakamoto merely states “[m]ost of the compounds were prepared by standard procedures,” giving no further guidance. See page 4529, Experimental Section. Additionally, Lumb never states how exactly the chelate forms, instead he explains how the stability constants are calculated for the alleged chelates through potentiometric determination. See page 690. In fact, in the abstract, Lumb discloses that the “probable” structures of the chelates are “suggested.” See page 690. It is unclear if the chelates were supposedly formed from the metal chloride and glutamic and aspartic acid solutions. See page 690, col. 2.

In light of the Ashmead ‘427 patent, it is doubtful that Nakamoto or Lumb created a true chelate, since Ashmead states “in order for a true chelate to be formed the mole ratio of protein hydrolysate ligand or amino acid ligand to metal must be at least 2:1 and the reaction conditions must favor the formation of a chelate by the removal of potentially interfering protons.” See col. 5, lines 59-63. In other words, even the references cited by the Examiner are at odds with respect to this issue. Ultimately, it is clear that neither Lumb nor Nakamoto teach fully coordinated chelates, and therefore, the Applicant respectfully requests that these rejections be withdrawn.

Additionally, the Examiner has asserted that the burden of establishing the present non-GMO chelate as non-obvious has shifted to the Applicant as the Examiner has provided several references containing metal amino acid chelates. Specifically, the Examiner stated that the Applicant has not “provided a showing of the differences between the prior art metal amino acid chelates and the instantly claimed metal amino acid chelates.” (underlining added)

The Applicant contends that the non-GMO amino acid chelates of the present application are inherently different than those previously disclosed. A non-GMO metal amino acid chelate is inherently different than a GMO metal amino acid chelate. The difference relates to the GMO and non-GMO starting materials. Each type has impurities associated with its manufacturing and cultivation processes. Those impurities are not the same. GMO materials by definition contain genetically modified organisms, which are chemically and structurally different than their non-genetically modified counterparts. As

such, the extraction of an amino acid from those two chemically and structurally different sources would provide a product that is inherently chemically different since no product is typically 100% pure and would contain the associated GMO or non-GMO products and impurities. While standard purification techniques should remove a majority of the contaminants, only the methods of the present invention could produce a composition that contains 0% of GMO organisms and associated products. The Applicant contends that the compositions of the present invention are chemically different than those of the prior art since the present method eliminates all GMO material inherently found in previous compositions and methods. It is noted that the Applicant is not claiming the chelate structure *per se*, but a composition (which is non-GMO as a whole) which includes the chelate structure. There is no teaching or suggestion in Ashmead '427 that the compositions prepared as a whole do not include GMO material. Absent such a suggestion, a rejection under 35 U.S.C. 103(a) is improper.

As further background, the present application addresses concerns associated with GMO and associated products. These concerns have been argued on a global scale. In 2004, Mendocino County, California became the first county in the United States to ban the production of GMOs. While arguments continue as to whether GMOs can or should be used in products sold to the public, the current application solves this problem by providing a non-GMO metal amino acid chelate composition which contains no GMO materials in the composition.

The Applicant renews its argument that the Hsu, Ashmead '424, and Ashmead '427 references do not teach non-GMO chelate compositions. In fact, the references never mention GMO or non-GMO at all. As these references have publication dates that are well within the time period where genetically modified organisms were very prevalent, these patents clearly teach of chelates, in fact, which would include compositions that could be formed as GMO compositions. The Applicant has claimed a specific narrow class of chelate compositions. The chelate compositions as a whole must contain non-GMO components. As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

The Examiner has rejected claim 34 and 43 over several general amino acid chelate references; specifically, Hsu, Ashmead '424, and Ashmead '427. However, none of these references provide a method of preparing or administering a non-GMO metal amino acid chelate composition. The Examiner states "that there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or amino acid from a genetically modified organism." Likewise, there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or amino acid from a non-genetically modified organism. In fact, this lack of teaching is precisely the reason the methods of the present invention do not read on the prior art. Independent claims 34 and 43 specifically require affirmative steps of making a non-GMO determinations for the metal and for the amino acid. Further, the final product must also be non-GMO, which according to the definition in the specification of non-GMO, is quite limiting. Relevant portions of the definitions from the specification are provided herein for the Examiner's convenience, as follows:

The term "GMO" is an acronym for the term "genetically modified organism(s)."

The term "GMO derivative" applies to any substance produced from, but not containing a genetically modified organism.

The term "non-GMO" herein includes compositions that are not GMOs, and also are not derived from GMOs. In other words, non-GMO compositions are not genetically modified of themselves, and are prepared by processes other than those which include the use of genetically modified organisms. Thus, amino acid chelates prepared in accordance with embodiments of the present invention, such as for human, animal, or foliar application, must not include or be produced with the utilization of genetically modified organisms.

None of the references provided by the Examiner refer to any such affirmative step of determination as required by claims 34 and 43, and further, as the final product must also be non-GMO, there is no teaching or suggestion in any of the references that the chelates described therein unambiguously meet this criteria. Even if the Examiner were to find a reference that includes no GMO material in the preparation, in order to read on the claimed

invention, that reference would also have to show that those materials were selected precisely because they are non-GMO, rather than by accidental selection. As such, the Applicant contends that the two independent method claims and subsequent dependent claims are clearly distinct over the cited references.

The Applicant wishes to remind the Examiner that the product by process inquiry for composition patentability has no relation to the inquiry for the method patentability of claim 34. Claim 34 is a method of making, not a composition. The product is not required to be novel for patentability of the method. The method is viewed independent of the product. With this in mind, the Examiner has not provided a reference that provides an affirmative step of non-GMO determination as part of the method in producing a metal amino acid chelate. Therefore, the Applicant respectfully requests that current 102 rejections be withdrawn.

As the Applicant has explained the novelty of the independent claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-17, 30-34, 37-40, 43 and 46-49 under 35 U.S.C. 103(a) as being unpatentable over combinations of several references.

Applicant does not deem it necessary to recite the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant, would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the four independent claims is provided herein, as the Applicants assert that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-17, 30-34, 37-40, 43 and 46-49 as being obvious in view various combinations of prior art. As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided as follows.

Composition Claims 1 and 17

The Examiner has combined two references, specifically Ashmead '427 and Izumi, to reject claims 1, 13-17, and 30-33. As previously discussed Ashmead '427 does not teach a non-GMO chelate composition. The Applicant renews the above arguments with respect to the Ashmead '427 reference. Additionally, Izumi does not teach a non-GMO chelate composition. No showing of any such language in any reference in the current office action has been made to make out a *prima facie* case of obviousness. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

Method Claims 34 and 43

The Examiner has combined two references, specifically Hsu and Izumi, to reject claims 34, 37-40, 43, and 46-49. As previously discussed, neither Hsu nor Izumi teach a non-GMO chelate composition. The Applicant renews the previous arguments with respect to the Hsu reference. Additionally, with respect to at least the method claims, the Examiner has failed to show any such language in any reference in the current office action related to affirmative steps to select non-GMO materials for use in preparing the non-GMO chelates. As such, no combination references cited by the Examiner teach or suggest every element of the claimed invention. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

Conclusion

In view of the foregoing, Applicants believe that claims 1-3, 5-10, 12-28, and 29-53 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone the undersigned so that such issues may be resolved as expeditiously as possible.

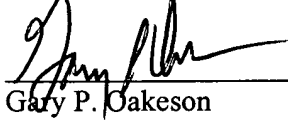
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Dated this 6th day of October, 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary P. Oakeson", is written over a horizontal line.

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